REMARKS

I. Request to Withdraw the Finality of the Office Action

In a telephone conference with Applicants' representative on June 16, 2003, the Examiner agreed with Applicants that the Office Action of April 11, 2003, was improperly made final. (Interview Summary, Paper No. 20.)

As the Examiner notes in the Interview Summary, the April 11, 2003, Office Action includes several new grounds of rejection, discussed in sections V(A), V(C), VI(B), VI(C), VI(D), and VI(E) below. Several of these new grounds of rejection were made against claims that had not been amended in response to the previous Office Action. For example, claims 16-21 are newly rejected under 35 U.S.C. § 103(a), yet these claims were not amended in the amendment filed January 21, 2003. In addition, the Office Action presents new grounds of rejection of claims 1 and 8 under 35 U.S.C. §§ 102 and 103. Yet, Applicants submit that the previous amendments of those claims were directed solely to matters of form and grammatical structure, and therefore, that the new grounds of rejection were not necessitated by Applicants' amendments. (See Applicants' remarks filed January 21, 2003, at page 4.) Nor were any of the new grounds of rejection necessitated by an Information Disclosure Statement under 37 C.F.R. § 1.97(c), as none has been filed in this application during the relevant period. Thus, neither of the conditions listed in M.P.E.P. § 706.07(a), under which an Office Action is made final, presently applies to this application.

Applicants respectfully request the Office to withdraw the finality of the Office Action mailed April 11, 2003, in order to speed prosecution and allow Applicants to

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present the enclosed amendments, remarks, and supporting documents. Applicants thank the Examiner for his assistance with this request.

II. Status of the Claims

Claims 1-26 are currently pending in this application. Claims 3, 6, and 7 are presently withdrawn from consideration due to an election of species requirement. Thus, claims 1-2, 4-5, and 8-26 are presently being examined.

Applicants amend claim 1 to recite that R^1 is "a substituted or unsubstituted C_5 - C_{23} alkyl radical, which is straight-chain or branched and may contain double and/or triple bonds." Claim 1 previously recited that R^1 is "a substituted or unsubstituted C_1 - C_{23} alkyl radical." This amendment is supported by the application as a whole, including original claim 1, and the specification at page 6, line 21, to page 7, line 11, and at page 11, lines 4-15.

Applicants amend claims 11, 12, and 22 to replace the term "reactive function" with "reactive group." This amendment does not alter the scope of the pending claims, as one of ordinary skill in the art would recognize that, in this context, "function" and "group" have the same meaning. Applicants also amend claims 10, 11, 16, 17, and 22 to depend from claim 1 or claim 8. These amendments are supported by the application as a whole, for example, by the original claims, the text at pages 19-23, and the working examples.

Finally, Applicants amend claim 9 solely to correct a typographical error in the figure depicting structure "F4." One of the oxygen atoms of that structure was inadvertently omitted from the figure in claim 9. The oxygen atom is present in the F4

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structure shown in Figure 2 of the application, however. Thus, this amendment does not change the scope of the claims or add new matter.

Applicants submit that these amendments do not introduce new matter or require a further search of the art. Therefore, they allow for immediate action. Applicants respectfully request their entry and the withdrawal of the finality of the Office Action.

Alternatively, if the Office does not withdraw the finality of the Office Action, Applicants request the entry of the amendments under 37 C.F.R. § 1.116, and submit that these amendments would clarify the issues for appeal.

III. Objections to Claims 9, 11, and 12

The Office objects to claim 9 because the F4 structure depicted in the claim lacks an oxygen atom that is present in the F4 structure shown in Figure 2. (Office Action at page 3.) Applicants therefore replace the F4 figure in the claim with the one shown in Figure 2.

The Office also objects to claims 11 and 12, as it prefers the terms "reactive group" or "functional group" to the term "reactive function" that is used in those claims. (The Office Action objects to claim 1. Because it is claim 11 that contains the term "reactive function," Applicants assume that this is a typographical error.) Solely to speed prosecution, Applicants amend each of these claims to replace "reactive function" with "reactive group."

In light of these amendments, Applicants request the withdrawal of the objections to claims 9, 11, and 12.

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IV. Claims 22-24 Are Enabled

The Office maintains the rejection of claims 22-24 under 35 U.S.C. § 112, first paragraph. (Office Action at pages 4-16.) The Office continues to assert that these claims are not enabled. Applicants traverse this rejection and present additional evidence of enablement.

Claims 22 and 23 recite a process of making a "pharmaceutical composition" that involves linking a conjugating compound of claim 1 or 8 to a "pharmaceutically active compound." Claim 24 recites a "pharmaceutical composition" comprising a compound of claim 1 or 8. As the specification illustrates, the purpose of the conjugation is to improve the cellular uptake of the "pharmaceutically active compound" so that it can reach its target more effectively. (*See* Applicants' Examples 7-8 and 16-18.) Following an election of species requirement, Applicants chose an oligonucleotide as the "pharmaceutically active compound" for initial examination.

The Office alleges that claims 22-24 are not enabled because antisense polynucleotides are allegedly unpredictable in general. According to the Office, "[t]he field of antisense, to date, does not provide guidelines by which antisense can be routinely delivered to generally any cell type *in vivo* (whole organism) at a concentration effective to result in a predictable therapeutic effect." (Office Action at page 13.) In other words, the Office contends that the prior art does not provide sufficient guidance for using antisense oligonucleotides in general. The Office also contends that Applicants' specification "fails to disclose any example of a therapeutic oligonucleotide" and does not disclose methods of treatment. (Office Action at pages 8 and 15.)

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Applicants submit that, in contrast to the Office's contentions, the specification discloses a number of oligonucleotides, enabled for pharmaceutical use, that can be conjugated according to the instant invention. Further, methods of treatment associated with those therapeutic oligonucleotides are provided in the art related to the oligonucleotide in question.

For example, the Office has issued a number of patents claiming "pharmaceutical compositions" comprising antisense oligonucleotides, as well as methods of *in vivo* treatment or diagnosis using such oligonucleotides. One example is Peyman et al., U.S. Patent No. 6,013,639, filed January 31, 1996, and issued January 11, 2000, which the Office cites in some of the rejections below. This patent claims "[a] pharmaceutical composition comprising one or more oligonucleotides . . ." from a list of 34 end-capped oligonucleotides, and also claims methods of treatment and diagnosis using those oligonucleotides. (*See* claims 43-45.) Applicants note that several of the oligonucleotides claimed in Peyman et al. are also described in the instant specification. (*See, e.g.*, oligos I and II of Peyman et al. listed in claim 6, which are also depicted at page 13, last two lines, of the present specification.) If the oligonucleotide compositions of Peyman et al. are enabled for disease treatment and diagnosis as of its filing date, why are conjugated versions of those same oligonucleode compositions not enabled? The Office provides no answer to this question.

In addition, U.S. Patent 5,885,970 ("the '970 patent"), filed June 7, 1995, and issued March 23, 1999, claims pharmaceutical compositions and methods of treating proliferative diseases with antisense oligonucleotides targeted to protein kinase C-alpha. (Exhibit A; see claims 1 and 19, for example.) SEQ ID NO:2 of the '970 patent is

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identical to SEQ ID NO:49 of the instant specification. The '970 patent's examples show that this oligonucleotide can, in either unmodified or 2' fluoro form, reduce the proliferation of several tumors in mice. (See examples 10 and 18-20. In those examples, the oligonucleotide is called ISIS # 3521.) Accordingly, this oligonucleotide, and a variety of other oligonucleotides described in the '970 patent, are all enabled for "treating a hypoproliferative condition associated with expression of human protein kinase C . . . " (See claims 1 and 19.) If no undue experimentation is required to use one of these oligonucleotides pharmaceutically, why would it require undue experimentation to use them in the conjugated form claimed here? Again, the office provides no answer.

U.S. Patents 5,767,102 ("the '102 patent"), filed January 7, 1997, and issued June 16, 1998, and 6,153,595 ("the '595 patent"), filed April 9, 1997, and issued November 28, 2000, both claim pharmaceutical compositions and methods of treating cytomegalovirus targets with antisense oligonucleotides. (Exhibits B and C; and see claims 1-4 of the '102 patent and claims 14-17 of the '595 patent.) Moreover, SEQ ID NO:1 of the '102 patent and SEQ ID NO:22 of the '595 patent is the same oligonucleotide as SEQ ID NO:12 presented in the instant specification at page 13. Examples 2-6 in the '102 patent show that this anti-cytomegalovirus oligonucleotide has pharmaceutical activity. If the Office considers the oligonucleotides claimed in the'102 and '595 patents to be enabled for methods of pharmaceutical treatment, why are they not enabled if they are used in the instantly claimed conjugated form? Once again, the Office provides no answer.

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All of these patents demonstrate that there were a number of oligonucleotides enabled for various pharmaceutical uses as of the time this application was filed, some of which are listed in Applicants' specification. Appropriate guidance for using those oligonucleotides in methods of treatment is provided by the art. All Applicants claim in claims 22-24 are compositions, or methods of making compositions, that improve the cellular uptake of oligonucleotides. In other words, Applicants' invention may be used to increase the uptake of any pharmaceutically active oligonucleotide. Thus, in contrast to the Office's contentions, Applicants do not need to provide treatment protocols to enable claims 22-24, because these are provided in the prior art.

Moreover, Applicants note that the test for enablement is not based on the quantity or complexity of the experimentation, but is based on whether the experimentation is "undue." M.P.E.P. § 2164.01; *In re Wands*, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988). As the Federal Circuit pointed out in *Wands*, "a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." 8 U.S.P.Q.2d at 1404, citation omitted; see also M.P.E.P. § 2164.06. Further, the specification need not include material that is known or available to those in the art, such as a treatment protocol. M.P.E.P. § 2164.05(a); *In re Buchner*, 18 U.S.P.Q.2d 1331, 1332 (Fed. Cir. 1991).

Applicants reiterate that claims 22-24 are enabled because one of ordinary skill in the art, based on the guidance provided in Applicants' specification and in the prior art, can, without undue experimentation: (a) identify and obtain a molecule that has known, credible pharmaceutical activity to serve as a "pharmaceutically active

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compound," (b) attach that molecule to a conjugating compound according to the claimed method, and (c) use the conjugated molecule as he would use the un-conjugated molecule. Each of these steps is either routine in the art, guided by the specification, or illustrated in the prior art.

As the above patents demonstrate, the present specification points one of ordinary skill in the art to several exemplary oligonucleotides that are enabled for pharmaceutical use or as pharmaceutical compositions. One of ordinary skill in the art may find additional pharmaceutically active molecules, including other oligonucleotides, in the scientific and patent literature. Thus, it does not require undue experimentation for one of ordinary skill in the art to identify an oligonucleotide or other molecule suitable for making a "pharmaceutical composition" according to this invention.

The specification shows how to attach the conjugating compounds of claims 1, 8, or 9 to an oligonucleotide and how to test whether cellular uptake is enhanced in a variety of cell types. (See, for instance, Examples 1-7 and Table 3.) If desired, a skilled artisan can also use routine affinity assays, such as gel shifts, filter binding, etc., or cell-based assays, such as *in situ* hybridization using a labeled oligonucleotide, in order to ensure that the conjugation does not interfere with the interaction between the oligonucleotide and its target.

After using the specification's guidance to make the claimed conjugates, one of ordinary skill in the art can then turn to the prior art related to the particular oligonucleotide he is working with, such as the patents mentioned above, for guidance as to how to use the oligonucleotide conjugates in the context of a method of pharmaceutical treatment or diagnosis. For example, if an experimenter wishes to

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conjugate the oligonucleotide of the '970 patent mentioned above, he may make the conjugate as described in Applicants' specification, test its cellular uptake in a relevant cell type, such as a tumor cell line, and then use the conjugated oligonucleotide in the mouse tumor assays as described in the '970 patent. As this example shows, all of the steps needed to make and use the conjugates of claims 22-24 are either routine assays known in the art, illustrated in Applicants' specification, or illustrated in the relevant prior art. Therefore, they do not require undue experimentation.

For all of the reasons above, Applicants submit that claims 22-24 are enabled and respectfully request the withdrawal of this rejection.

V. Claims 1-2, 4-5, 8, 10-12, 15, and 22-25 Are Novel

A. Rejection of Claims 1, 2, 4, 5, 10, and 22-25 under 35 U.S.C. § 102(b); Radhakrishnan Iyer et al.

The Office asserts that claims 1-2, 4-5, 10, and 22-25 are anticipated by an article by Radhakrishnan Iyer et al. (*Bioorg. Med. Chem.*, 7: 871-6 (1997)). (Office Action at pages 16-17.) The Office asserts that Iyer et al. teaches an aryl radical according to claim 1. Applicants traverse this rejection. Applicants also note that claim 1 is now amended to recite that R^1 is "a substituted or unsubstituted C_5 -C_{23} alkyl radical, which is straight-chain or branched and may contain double and/or triple bonds," while claims 10 and 22 are amended to depend from claim 1 or claim 8.

In order for a reference to anticipate a claim, the reference must teach each and every element of that claim, either expressly or inherently, and in as much detail as the claim itself. M.P.E.P. § 2131; *Verdegaal Bros. v. Union Oil Co. of Calif.*, 2 U.S.P.Q.2d

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1051, 1053 (Fed. Cir. 1987); *Richardson v. Suzuki Motor Co.*, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). None of the compounds depicted in Iyer et al. contains an R^1 group as claimed in claims 1, 2, 4, 5, 10, or 22-25. For example, the group at position "R" in Iyer et al. is either a substituted phenyl, rather than an alkyl radical, or is a group with less than 5 carbon atoms. (See Iyer et al. at page 872, Scheme 1.) Thus, Iyer et al. does not recite element R^1 as Applicants claim and cannot anticipate Applicants' claims. Therefore, Applicants respectfully request that this rejection be withdrawn.

B. Rejection of Claims 11, 12, and 15 under 35 U.S.C. § 102(b); Cook et al.

The Office rejects claims 11, 12, and 15 over Cook et al. (WO 94/01448). (Office Action at page 17.) The Office particularly cites the structure shown at page 6, line 4, of Cook et al.

Applicants note that claim 11 is amended herein to depend from claim 1 or claim 8, and that the Office considers claims 1 and 8 to be novel and nonobvious over Cook et al. (Office Action at page 3.)

Applicants traverse this rejection because the compound at page 6, line 4, of Cook et al. does not fall within the genus of conjugating compounds of claims 11, 12, or 15. Instead, in Cook et al., the equivalent of R^1 is not "a substituted or unsubstituted C_5 - C_{23} alkyl radical, which is straight-chain or branched and may contain double and/or triple bonds," as Applicants claim, for example in claim 1, but a heterocyclic ring fused to the nitrogen atom at position X. Such a fused ring system is not contemplated by the recitation of "a straight-chain or branched" substituent. Indeed, a ring is not a "straight

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chain," or a "branched" chain. In addition, no other compound disclosed in Cook anticipates any of Applicants' claims.

Thus, Applicants request the withdrawal of this rejection.

C. Rejection of Claims 1, 2, 8, 24, and 25 under 35 U.S.C. § 102(a); Cuthbertson et al.

The Office rejects claims 1, 2, 8, 24, and 25, asserting that they are anticipated by Cuthbertson et al. (Office Action at page 18.) Applicants note that German Application No. 19935302.6-44, to which this application claims priority, was filed on July 28, 1999, prior to the publication of Cuthbertson et al on November 4, 1999. As the Office suggests, Applicants enclose a certified English-language translation of the German priority application in order to perfect the priority claim. (Exhibit D.)

The subject matter of claims 1, 2, 8, 24, and 25 is supported, for example, at pages 6-8 and page 22, lines 11-28, as well as at other locations throughout the translated German application as a whole. Therefore, Applicants request the withdrawal of this rejection.

VI. Claims 11, 13-14, 16-21 and 26 Are Nonobvious

A. Rejection of Claims 11, 13, and 14 under 35 U.S.C. § 103(a); Cook et al.

The Office maintains the rejection of claims 11, 13, and 14 as allegedly obvious over Cook et al. (Office Action at page 19.) Applicants traverse this rejection.

First, claim 11 is amended to depend from claim 1 or claim 8, which the Office acknowledges to be both novel and nonobvious over Cook et al. (Office Action at

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pages 3 and 19; Office Action of October 18, 2002, at pages 18-19.) Claim 11 must also be novel and nonobvious by virtue of its dependence on claim 1 or claim 8.

Second, a reference, or combination of references, cannot render a claim obvious unless it fairly teaches or suggests all of the elements of that claim. M.P.E.P. § 2143. Applicants submit that, for the reasons stated above in section V(B), Cook et al. does not teach a conjugate as claimed in claims 1 or 8, from which claims 11, 13, and 14 depend. Because Cook et al. fails to teach essential elements of Applicants' claims, it cannot render the processes of claims 11, 13, or 14 obvious. Therefore, Applicants request the withdrawal of this rejection.

B. Rejection of Claims 16-19 and 21 under 35 U.S.C. § 103(a); Peyman et al. and Iyer et al.

The Office rejects claims 16-19 and 21, asserting that they are obvious over Peyman et al. (U.S. Patent No. 6,013,639) in view of Iyer et al., discussed above in section V(A). (Office Action at pages 20-21.) Applicants traverse this rejection, and also note that claims 16 and 17 are amended to depend from claim 1 or from claim 8.

First, Applicants submit that Peyman et al. was published after the filing date of German Application 19935302.6-44, to which Applicants claim priority. Applicants submit an English-language translation of the German priority application showing that Applicants were in possession of the claimed invention prior to the publication of Peyman et al. (Exhibit D.) Thus, Peyman et al. does not qualify as either § 102(a)- or § 102(b)-type prior art against the instant application.

Second, Peyman et al. does not qualify as prior art under 35 U.S.C. § 103(c) because it was commonly owned with the present invention at the time the present

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invention was made. (See the Statement of Common Ownership below and Exhibit E; see also M.P.E.P. § 706.02(l)(2) and § 804.03.)

Third, as stated above, a combination of references cannot render a claim obvious unless it fairly teaches or suggests all of the elements of that claim. M.P.E.P. § 2143. Iyer et al. does not teach or suggest the conjugates of either claim 1 or claim 8, recited in step (a) of claims 16 and 17. In addition, the Office admits that Peyman et al. does not teach an aryl linkage of formula I. (Office Action at page 20.) Instead, the Office relies upon Peyman et al. for teaching methods of delivering alkyl-conjugated oligonucleotides to tumor cells. The Office asserts that it would have been obvious for one of ordinary skill in the art to modify the composition of Peyman et al. with the aryl linkage of Iyer et al. However, because Iyer et al. does not teach the aryl linkage of either claim 1 or claim 8, a combination of Peyman et al. with Iyer et al. would not lead to Applicants' claimed invention. Because the combination of Iyer et al. and Peyman et al. does not teach or suggest all of the elements of Applicants claims, it cannot rise to the level of a *prima facie* case of obviousness. *See* M.P.E.P. § 2143.

Applicants request the withdrawal of this rejection for all of the above reasons.

C. Rejection of Claims 16-20 under 35 U.S.C. § 103(a); Baker et al.; Peyman et al., and Iyer et al.

The Office rejects claims 16-20 over Baker et al. (U.S. Patent No. 6,080,580) in view of Peyman et al. and Iyer et al. (Office Action at pages 21-22.) Applicants traverse this rejection, again noting that claims 16 and 17 now depend from claims 1 and 8.

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The Office relies on Iyer et al. and Peyman et al. as discussed in the preceding section, and relies on Baker et al. for a teaching of delivering lipiphilic oligonucleotide conjugates to human cells. The Office admits that, like Peyman et al., Baker et al. does not teach an aryl radical linkage as in formula I.

First, Peyman et al. and Baker et al. were both published after the filing date of the German priority application 19935302.6-44, and do not qualify as either § 102(a)- or § 102(b)-type prior art against the instant application. Applicants submit an English-language translation of the German priority application to show that Applicants were in possession of the claimed invention prior to the publication of either Baker et al. or Peyman et al. (Exhibit D.)

Second, Peyman et al. does not qualify as prior art under 35 U.S.C. § 103(c) because it was commonly owned with the present invention at the time the present invention was made. (See the Statement of Common Ownership below and Exhibit E; see also M.P.E.P. § 706.02(l)(2) and § 804.03.)

Third, Iyer et al. does not teach or suggest the conjugates of either claim 1 or claim 8, recited in step (a) of claims 16 and 17. In addition, the Office admits that neither Baker et al. nor Peyman et al. teaches or suggests the aryl radicals of these conjugates. Accordingly, this combination does not teach or suggest all of the elements of Applicants' claims. Because a *prima facie* case of obviousness must be based upon art that teaches or suggests all of the claim elements, this combination does not present a *prima facie* case. *See* M.P.E.P. § 2143.

Applicants request the withdrawal of this rejection for all of the above reasons.

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D. Rejection of Claim 26 under 35 U.S.C. § 103(a); Iyer et al.

The Office rejects claim 26 as allegedly obvious over Iyer et al. (Office Action at pages 22-23.) Applicants traverse this rejection.

The Office asserts that Iyer et al. teaches conjugates according to claim 1, from which claim 26 depends. However, Iyer et al. does not teach conjugates according to claim 1, as presently amended. (See the discussion of Iyer et al. in section V(A) above.) For this reason, Iyer et al. does not teach or suggest all of the elements of claim 26. Because a *prima facie* case of obviousness must be based upon a teaching or suggestion of all of the elements of a claim, Iyer et al. does not support a *prima facie* case. Applicants therefore respectfully request its withdrawal.

E. Rejection of Claims 26 under 35 U.S.C. § 103(a); Cuthbertson et al.

Finally, the Office rejects claim 26 as allegedly obvious over Cuthbertson et al. (Office Action at page 23.) Applicants also traverse this rejection.

Applicants note that Cuthbertson et al. was published after the filing date of German priority application 19935302.6-44. Applicants provide an English-language translation of the priority application to perfect their claim for priority. (Exhibit D; and see previous section V(C).) Thus, Applicants request the withdrawal of this rejection.

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STATEMENT OF COMMON OWNERSHIP OF U.S. PATENT NO. 6,013,639

United States Patent No. 6,013,639 ("Peyman et al.") was filed on January 31, 1996, as Application No. 08/594,452, and was issued on January 11, 2000. The instant application was filed on July 27, 2000, and claims priority to German Application No. 19935302.6-44, filed on July 28, 1999.

At the time the instant, claimed invention was made, it was commonly owned with Peyman et al. by Hoechst Aktiengesellschaft, which is now known as Aventis Pharma Deutschland GmbH. The assignment records for Peyman et al. are attached in Exhibit E. Please note that a second assignment recorded at Reel 011309, Frame 0261, was mistakenly accorded to Peyman et al. The attached documents show that this second assignment should have been accorded to Application No. 09/594,452.

Therefore, Peyman et al. does not qualify as prior art against the present, claimed invention under 35 U.S.C. § 103(c). (See M.P.E.P. § 706.02(l)(1)-(2) and § 804.03.)

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CONCLUSION

Applicants respectfully request the withdrawal of the finality of the present Office Action, and the entry of this Amendment. Applicants also submit that the examined subject matter is in condition for allowance, and hence, request the Office to continue examination of the non-elected species to the extent necessary to determine the patentability of the generic claims in accordance with 37 C.F.R. § 1.141 and M.P.E.P. § 803.02.

This Amendment is accompanied by a Petition for a Two-Month Extension of Time to September 11, 2003. Please grant any extensions of time required to enter this response and charge any required fees not submitted herewith to Deposit Account No. 06-0916.

Respectfully submitted,

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Dated: August 14, 2003

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